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PPLICATION NO.	FIL	ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/639,614	39,614 08/11/2003		Katherine S. Tweden	7883.97-02	5399
22852	7590	12/29/2004		EXAMINER	
FINNEGAT	N, HENDI	ERSON, FARAB	PELLEGRINO, BRIAN E		
1300 I STRE	ET, NW			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20005				3738	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)						
Office Action Cummons	10/639,614	TWEDEN ET AL.						
Office Action Summary	Examiner	Art Unit						
	Brian E Pellegrino	3738						
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply if NO period for reply is specified above, the maximum statutory period we Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	ely filed  will be considered timely. the mailing date of this communication.  O (35 U.S.C. § 133).						
Status		•						
1) Responsive to communication(s) filed on 11 A	)⊠ Responsive to communication(s) filed on <u>11 August 2003</u> .							
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	This action is FINAL. 2b)⊠ This action is non-final.							
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.								
Disposition of Claims								
4)⊠ Claim(s) <u>18-37 and 41-68</u> is/are pending in the application.								
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.								
6)☐ Claim(s) is/are rejected.								
, , ,	Claim(s) is/are objected to.							
8) Claim(s) 18-37 and 41-68 are subject to restriction and/or election requirement.								
Application Papers								
9) The specification is objected to by the Examiner.								
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
	diffilier. Note the attached Office	Action of formal 10 102.						
Priority under 35 U.S.C. § 119								
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a) ☐ All b) ☐ Some * c) ☐ None of:								
1. Certified copies of the priority documents have been received.								
<ul> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>								
application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.								
Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)								
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	5)  Notice of Informal P 6)  Other:	atent Application (PTO-152)						

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## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 18-34, drawn to a device for transferring blood from a vessel to another area with a myocardial liner, classified in class 604, subclass 8.
- II. Claims 35-37, drawn to a method of supporting a vascular wall, classified in class 606, subclass 198.
- III. Claims 41-68 drawn to a stent and methods of providing blood flow from a heart chamber to a coronary vessel with the stent having an agent and an outer covering or both an inner and outer covering, classified in class 623, subclass 1.43.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions such as Invention I being performed to provide access to the vessel and form a delivery route for the apparatus. Invention III is methods of delivering apparatus with an agent to a site within the heart. Invention I does not involve delivery of apparatus to the heart.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2)

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that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the stent covering with the agent is not required to be in the myocardial portion as in the subcombination claims (Invention I). The subcombination has separate utility such as a shunt in any bypass with the heart, not just across the myocardium.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

<u>Apparatus</u> <u>Lining and coverings</u>

Species I: Figs. 1,2. Specie A: inner

Species II: Fig. 3. Specie B: outer

Species III: Fig. 4. Specie C: both

Species IV: Fig. 5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (7:30am-5pm) 2nd F (7:30-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738 Primary Examiner Brian E. Pellegrino

Bran & Pellegrino